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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,722	03/29/2004	Christoph Reinhard	59516-47/PP-01699.003	1686

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,722	REINHARD ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-18 are pending in the instant application.

Claims 1-18 are subject to restriction as detailed below:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Election/Restrictions

Group I. Claims 1-6, 8-12, and 16-18, drawn to an isolated Akt3 inhibitor, wherein said inhibitor is an antisense or ribozyme, classifiable in class 536, subclass 24.5.

Group II. Claims 1, 8, and 9, drawn to an isolated Akt3 inhibitor, wherein said inhibitor is a protein, classifiable in class 530, subclass 350.

Group III. Claims 1 and 7-9, drawn to an isolated Akt3 inhibitor, wherein said inhibitor is an antibody, classifiable in class 424, subclass 7.24.

Group IV. Claims 1, 8, and 9, drawn to an isolated Akt3 inhibitor, wherein said inhibitor is a small organic molecule, classifiable in class 435, subclass 6.

Group V. Claims 13-15, drawn to a method of decreasing the expression of Akt3 in a mammalian cell comprising administering an isolated Akt3 inhibitor, wherein said inhibitor is an antisense or ribozyme, classifiable in class 514, subclass 44.

Group VI. Claims 13 and 15, drawn to a method of decreasing the expression

of Akt3 in a mammalian cell comprising administering an isolated Akt3 inhibitor, wherein said inhibitor is a protein, classifiable in class 514, subclass 2.

Group VII. Claims 13 and 15, drawn to a method of decreasing the expression of Akt3 in a mammalian cell comprising administering an isolated Akt3 inhibitor, wherein said inhibitor is an antibody, classifiable in class 424, subclass 134.1.

Group VIII. Claims 13 and 15, drawn to a method of decreasing the expression of Akt3 in a mammalian cell comprising administering an isolated Akt3 inhibitor, wherein said inhibitor is a small organic molecule, classifiable in class 514, subclass 2.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Searching the inventions of Groups I-IV together, in one application, would impose a serious search burden. The inventions of Groups I-IV are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions of Groups I-IV are unrelated and distinct because they are different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the isolated antisense Akt3 inhibitor of Group I would not necessarily encompass all of the art relevant to the isolated protein Akt3 inhibitor of Group II. Similarly, a search of the isolated antibody Akt3 inhibitor of Group III would not necessarily encompass all of the art relevant to the isolated small organic molecule Akt3 inhibitor of Group IV. Since a search of Group I would not encompass all the art relevant to Group II, and a search of Group III would not encompass all of the art relevant to Group IV, the inventions are not coextensive. Since the search for Groups I-IV are not entirely coextensive, it would be burdensome to search the inventions of these Groups together in one application. Therefore, they are patentably distinct from each other.

Searching the inventions of Groups V-VIII together would impose a serious search burden. Although the methods of Groups V-VIII are related because they recite

a method of decreasing the expression of Akt3 in a mammalian cell comprising administering an isolated Akt3 inhibitor, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons: They employ different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the method of decreasing the expression of Akt3 in a mammalian cell comprising administering an antisense or ribozyme inhibitor of Akt3 of Group V would not encompass all of the art relevant to the method of decreasing the expression of Akt3 in a mammalian cell comprising administering protein inhibitor of Akt3 of Group VI. Similarly, a search of the method of decreasing the expression of Akt3 in a mammalian cell comprising administering an antibody inhibitor of Akt3 of Group VII would not necessarily encompass all of the art relevant to the method of decreasing the expression of Akt3 in a mammalian cell comprising administering small organic molecule inhibitor of Akt3 of Group VIII. They are materially distinct methods which differ in reagents used and criteria for success. Thus, they are patentably distinct from each other.

Groups I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated antisense or ribozyme inhibitor of Akt3 can be as a hybridization probe in a method of identifying Akt3 mRNA expression, which is an entirely different process than a method of decreasing the expression of Akt3 in a mammalian cell as recited in Group V. Therefore, Group I is distinct from Group V, since the composition of Group I can be used in a materially distinct method than that recited in Group V.

If Group I is elected, claims 5, 11, 12, and 17 are subject to an additional restriction since they are not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 5, 11, 12, and 17 specifically claims antisense molecule inhibitors of Akt3, wherein said antisense molecules comprise SEQ ID NOs: 1-6 and 12-19. Although the antisense molecule inhibitors claimed are each complementary to a nucleic acid molecule encoding Akt3, the instant antisense molecule inhibitors are considered to be unrelated, since each antisense molecule claimed is structurally and functionally independent and distinct for the following reasons: each antisense molecule has a unique nucleotide sequence and each antisense molecule targets a different and specific region of a nucleic acid molecule encoding Akt3 (per Applicant's Table I in the instant specification). As such the Markush/genus of antisense molecule inhibitors of Akt3 in claims 5, 11, 12, and 17 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the antisense molecule inhibitors claimed in claims 5, 11, 12, and 17 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense molecules. In view of the foregoing, one (1) antisense molecule inhibitor of Akt3 is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) antisense molecule inhibitor of Akt3 from claims 5, 11, 12, and 17. Note that this is not a species election.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tcg
August 7, 2006